



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Secretary's Advisory Committee on  
Human Research Protections  
Washington, DC 20201

JAN 10 2013

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The Honorable Kathleen Sebelius  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Ms. Sebelius:

On behalf of the Secretary's Advisory Committee on Human Research Protections (SACHRP), I respectfully submit for your consideration recommendations relevant to the Department of Health and Human Services (HHS) human subjects protection regulations at 45 CFR part 46. These recommendations, stemming from the SACHRP Subcommittee on Harmonization and Subpart A Subcommittee, were passed by SACHRP at their October 2012 meeting.

**Recommendations from the Subcommittee on Harmonization**

On October 28, 2009, SACHRP approved a recommendation establishing a Subcommittee on Harmonization (SOH). SACHRP's charge to this subcommittee was to identify and prioritize areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. The Subcommittee will develop recommendations for consideration and possible adoption by SACHRP, to harmonize and simplify these guidelines and regulations. The goal of this subcommittee effort is to reduce unnecessary burdens on research efforts, thus resulting in better allocation of research resources and promoting the safety and welfare of human subjects.

SACHRP approved the following recommendations and comment from this subcommittee on October 10, 2012:

*IRB Knowledge of Local Context (Attachment A)*

*Commentary on OHRP and FDA Draft Guidance Documents on Transfer of Research to New Institutions*  
(Attachment B)

**Recommendations from the Subpart A Subcommittee**

On October 5, 2004, SACHRP approved a recommendation establishing a Subpart A Subcommittee (SAS). SACHRP's charge to this subcommittee was to review and assess all provisions of subpart A of 45 CFR part 46 (HHS' codification of the Federal Policy for the Protection of Human Subjects, also known as the Common Rule) and relevant Office for Human Research Protections (OHRP) guidance documents, and based on this review and ongoing assessment, to develop recommendations for consideration by SACHRP in three categories: (1) recommendations on interpretation of subpart A provisions; (2) recommendations for development of new, or modification of existing, OHRP guidance; and (3) recommendations for possible revision of subpart A.

The goals of this review and assessment of subpart A of 45 CFR part 46 are threefold: (1) to enhance the protection of human subjects; (2) to reduce, where possible, regulatory burdens that do not contribute to the protection of subjects in a meaningful way; and (3) to promote scientifically and ethically valid research. To that end, SACHRP approved the following recommendations and comment from this subcommittee on October 9 and 10, 2012:

*Recommendations on Investigator Responsibilities* (Attachment C)

*Recommendations on Informed Consent and Waiver of Consent* (Attachment D)

On behalf of SACHRP, I would like to thank you for your consideration of this report. The committee, the Subpart A Subcommittee and the Subcommittee on Harmonization have been actively working in pursuit of their charges, and we look forward to continuing this work to enhance human subjects protections for the benefit of all Americans.

Sincerely,

/ signed /

Barbara E. Bierer, M.D.  
Former Chair, Secretary's Advisory Committee  
on Human Research Protections  
(SACHRP)

cc: Jerry Menikoff, M.D., J.D., Executive Secretary, SACHRP  
Julia Gorey, J.D., Executive Director, SACHRP